Message

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Sent: 5/23/2019 2:21:21 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Vermont on Path to Strictest School Lead Tests in Nation

By Adrianne Appel

Posted May 22, 2019, 5:58 PM

Vermont is poised to require the strictest school lead testing requirements in the nation under a measure headed to the governor's desk.

Nonstick Chemical Bills Not Ready for Prime Time, Barrasso Says

By Sylvia Carignan

Posted May 22, 2019, 12:47 PM

The head of the Senate's environment panel is wary of regulating a class of thousands of chemical compounds at once—a position that threatens progress toward a legislative package addressing the ubiquitous compounds' presence as environmental contaminants.

EPA, Congress Vary on Compelling Nonstick Chemical Reports (1)

By Pat Rizzuto and Sylvia Carignan

Posted May 22, 2019, 10:30 AMUpdated May 22, 2019, 12:44 PM

The EPA is floating the idea of requiring companies to report their emissions, disposal, and other releases of certain nonstick chemicals.

EPA Targets December for Big Nonstick Chemicals Decision (2)

By David Schultz

Posted May 22, 2019, 10:17 AMUpdated May 22, 2019, 4:31 PM

Despite pressure from lawmakers and environmentalists, the EPA said it will not announce until December how it plans to regulate two prevalent, potentially toxic chemicals that are contaminating drinking water supplies in communities across the country.

EPA Drops Rules for Cleaning Solvent, Widely Used Chemicals

By Pat Rizzuto

Posted May 22, 2019, 9:58 AM

Planned EPA rules to control how companies use a cleaning solvent and a group of chemicals that have kept autos running and airplanes flying were dropped from a list of regulations under development.

INSIDEEPA.COM ARTICLES

Revised EPA Agenda Sees Deadlines Slip For Major Obama Rule Rollbacks

EPA in its just-updated Unified Agenda of pending regulations is acknowledging that its deadlines have slipped considerably for many high-profile rollbacks of Obama-era rules, including climate standards for power plants and vehicles, as well as the 2015 Clean Water Act (CWA) jurisdiction standard.

Appropriators Spurn GOP Efforts To Scale Back EPA Power, FY20 Budget

House Democrats have rejected Republican attempts to fight funding increases for EPA enforcement or restore riders limiting EPA's authority, a trend that appears likely to repeat itself during subsequent floor action on the agency's fiscal year 2020 spending bill, which is expected in June at the earliest.

Senators Tout Bipartisanship On PFAS But Barrasso Seeks To Narrow Bills

Environment committee senators are pledging to take a bipartisan approach that includes environmentalists and industry as they seek to address polyfluoroalkyl substances (PFAS), though committee Chairman John Barrasso (R-WY) is indicating that while the bills under review enjoy bipartisan support, they will have to be narrowed to win his approval.

SAB Investigates Rule 'Co-Benefits' As EPA Eyes Cost Analysis Overhaul

EPA's Science Advisory Board (SAB) is seeking to investigate the agency's valuation of "co-benefits" in its Clean Air Act rules and is planning a new report on the topic, just as EPA overhauls its approach to cost-benefit analysis for rules to downplay its prior emphasis on co-benefit pollution reductions to help justify the cost of regulations.

GREENWIRE ARTICLES

White House updates rule-busting agenda

Niina Heikkinen, E&E News reporter Published: Wednesday, May 22, 2019

President Trump waved from the balcony of the family residence of the White House in this file photo from last month. Shealah Craighead/White House/Flickr

The White House this morning released its progress report on efforts to kill or curtail regulations across the government.

The Office of Information and Regulatory Affairs released the biannual report, which tracks agencies' short- and long-term regulatory goals, with little fanfare.

"This Agenda update shows our commitment to regulatory reform and a preview of the actions agencies have planned for the next 12 months," acting OIRA Administrator Paul Ray said in an emailed statement to E&E News.

"This will be another impactful year for local communities, small businesses, and individual Americans, as they witness elimination of barriers to financial success and personal liberty," said Ray.

https://www.eenews.net/greenwire/2019/05/22/stories/1060379715

CHEMICAL WATCH ARTICLES

EU seeks delegated act for titanium dioxide classification proposal

Move signals change of legal course for CLP classification

22 May 2019 / Built environment, Classification, CLP Regulation, Europe, Substances of concern

The European Commission has changed tack in its attempt to classify titanium dioxide as a carcinogen and will now try to push through the CLP proposal in the form of a delegated act, sources at the EU executive have said.

The shift in legal course means the Commission will not now be seeking a vote on the classification in the REACH Committee as in previous CLP decisions, "as it will not be competent for CLP anymore", they said.

Instead, it will consult on the draft Regulation that contains titanium dioxide classification with a Commission expert group, most likely the competent authorities for REACH and CLP (Caracal), they added. Discussions are expected in the summer, possibly at the next Caracal meeting set for 1-2 July.

Titanium dioxide has widespread uses, mainly in spray paints and varnishes, but also in cosmetics and spray-on sunscreen products. It is also used as a catalyst in cement.

The decision to bypass the REACH Committee on the issue comes amid changes on the horizon in the EU regulatory procedure due to the alignment 'omnibus act', expected to enter into force in the summer.

This aligns the existing EU legislation to the legal framework introduced by the Treaty of Lisbon and consequently amends the Commission's empowerments.

Once the omnibus act is adopted, CLP and other Commission acts that have so far been subject to the regulatory procedure with scrutiny – the comitology procedure involving a committee vote – will be dealt with through delegated acts, according to the sources.

Bumpy ride

Titanium dioxide's classification as a category 2 carcinogen has been a bumpy ride since the Commission updated its proposal in January to restrict the CLP entry to mixtures in powder form, arguing that the substance's carcinogenicity is only associated with inhalation.

The change sparked a wave of criticism from NGOs accusing the Commission of ignoring scientific advice. It also led to concerns from industry over the handling of waste containing the substance when it can be in powder, solid or liquid forms.

The Commission reacted by announcing plans in March to amend the waste guidance and make room for titanium dioxide, only to be met with further criticism.

The current proposal suggests that mixtures such as concrete in wet state or cement in solid form that may contain titanium dioxide particles will not be classified under CLP, and when discarded will not be classified as hazardous waste as long as they remain in that form or physical state.

The Commission said it would follow an internal process for the adoption of a new version of the technical waste classification guidance, and organise a discussion with the waste expert group.

But resistance to the CLP proposal and waste amendment plan remains strong.

The Titanium Dioxide Manufacturers Association (TDMA) said the proposed waste guidance is not legally binding and is open to interpretation in different member states. "It is insufficient to resolve the issue and avoid negative impacts on the circular economy," a spokesperson said.

Legal steps

The Commission has put the 14th Adaptation to Technical Progress amendment to the CLP regulation, which includes titanium dioxide, before the REACH Committee for a discussion several times. But it has so far refrained from taking a vote on the issue, with a number of EU member states remaining opposed to it.

The Commission may now be able to fast track the proposal through a delegated act in the summer, although it would still face the scrutiny of the European Parliament and Council.

Once the Commission adopts a delegated act, Parliament and Council generally have two months to formulate any objections. If they do not, the delegated act enters into force.

If either Parliament or Council, or both, object, the delegated act is then rejected, but they need to provide a motivation for the objection.

Meanwhile TDMA called for the 14th ATP to continue without titanium dioxide "to allow resolution of the many downstream impacts and to consider other regulatory approaches" for the substance.

Clelia Oziel

Europe correspondent

Related Articles

- NGOs urge EU states to reject changed titanium dioxide classification proposal
- EU titanium dioxide classification proposal hits waste obstacle
- EU waste amendment for titanium dioxide classification faces opposition
- UN rapporteur 'deeply concerned' about titanium dioxide labelling proposal

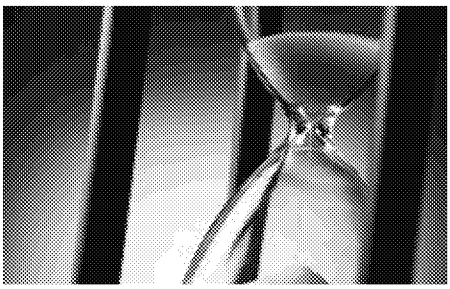
Further Information:

- Omnibus act

South Korea's MoE dismisses K-REACH pre-notification concerns

Industry claims meeting 30 June deadline will be 'difficult'

22 May 2019 / K-REACH, South Korea, Substance registration



South Korea's environment ministry has dismissed industry claims that it will find it difficult to meet the pre-notification deadline of 30 June for K-REACH.

The Ministry of Environment (MoE) says it has received reports from importers that they are struggling to gather information on substance names, which are necessary for pre-notification, from overseas chemical companies. This is because they are worried about the adequacy of confidential business information (CBI) protection.

This has led to calls to either change the pre-notification requirements or to extend the deadline. The Korea Economic Research Institute suggested to the ministry that the substance names required for pre-notification be substituted for the overseas company name.

The amended K-REACH requires all existing substances that are manufactured or imported in volumes of a tonne or more each year to be registered.

By 30 June this year, companies must 'pre-notify' these existing substances, according to their hazardousness and volume, in order to be granted a grace period to complete registration (see box).

MoE response

A statement issued by the MoE says that companies have had sufficient notice to prepare and have been included in public consultation on the changes. The major K-REACH amendment containing the pre-notification requirement, which was promulgated in March 2018, was "first proposed in December 2016", it says.

The MoE has rejected the idea of not requiring the substance name for pre-notification. A key purpose of pre-notification, it says, is to identify the substances that companies manufacture or import. This will enable companies to form and manage consortia for joint substance registration. This is especially important, the ministry says, for consortia dealing with substances manufactured or imported in volumes of 1,000 tonnes or more, which must be registered by 31 December 2021.

The MoE statement reminds companies that, if overseas suppliers do not want to disclose substance information to domestic importers because of concerns over CBI, they can carry out pre-notification through directly appointed only representatives (ORs).

Companies have complained that they face closure because they cannot obtain the information they need and, therefore, cannot import substances. The MoE says it has held numerous meetings and discussions with industry but has not heard of cases that reflect this complaint. Rather, it says, some domestic companies have welcomed the regulation as it can enhance international competitiveness.

OR difficulties

Junho Lee of consultancy CIRS in China has told Chemical Watch some major global chemical companies are finding it difficult to establish ORs.

Mr Lee advises companies to remember that the approvals process for pre-notification takes around two weeks.

Overseas manufacturers, says Mr Lee, must appoint an OR as soon as possible. To meet the 30 June deadline, this will require an appointment by the end of May at the latest, he says.

But some companies are finding it difficult to collect information on the large number of substances sold by major companies and their potential distribution in South Korea, which is information that must be included in the pre-notification. Because of this, some are struggling to meet the deadline, he says, despite starting preparations for ORs last year.

Pre-notification

Companies looking to manufacture or import one tonne or more a year of an existing substance need to 'pre-notify' the Korea Environment Corporation (Keco), an agency working under the MoE, before 31 June in order to be granted a grace period for registration.

The grace periods are:

- for substances imported/manufactured in volumes of 1,000 tonnes or more a year, or one tonne or more of CMR substances: 31 December 2019;
- volumes between 100-1,000 tonnes: 31 December 2022;
- volumes between 10-100 tonnes: 31 December 2025; and
- volumes between 1-10 tonnes: 31 December 2028.

However, if a company has already manufactured or imported one tonne or more of an existing substance in any year between 2016-2018, it must pre-notify by 30 June to continue manufacturing/importing.

Pre-notifications must be submitted through Keco's chemical substances information process system and include:

- the substance name;
- the annual volume of manufacture/import;
- details on the classification and labelling of substance;
- the manufacturer or importer's business name, address and contact details; or
- if an overseas manufacturer has appointed an OR, the business name of the importer and their contact details.

If a company does not pre-notify, the environment ministry can order a suspension of manufacture, import or use of the substances.

Sunny Lee

Asia editor

Related Articles

- US voices concern over South Korea's K-REACH implementation
- K-REACH draft CBI naming and exemption rules released
- Existing chemical substances lists (2019 revision)
- CMR substances (K-REACH) 2018

Further Information:

- MoE press release (in Korean)

US EPA looks to move on controversial science transparency rule

Consumer advocates say 2019 completion would be 'quite the feat'

22 May 2019 / Confidentiality & right-to-know, Data, United States

The US EPA still hopes to finalise its controversial science transparency rule in the near future, attendees of a recent NGO webinar heard. But despite recent indications that the rule is moving forward, advocates say the goal of a December timeline might be a heavy lift.

The proposal – which would overhaul the EPA's scientific evaluation process and require studies underlying regulations be publicly available and independently verifiable – was listed on the agency's long-term regulatory action in October 2018, indicating that it had been delayed until at least early 2020.

However, Administrator Andrew Wheeler seemed to reverse course in a December 2018 interview, saying the agency had plans to finalise the rule before the end of 2019. And on a 9 May Science Response Network webinar, attendees heard that this plan remains in place.

"The staff have been told that [agency leaders] want it to come out by the end of this calendar year," said Tracey Woodruff, professor of reproductive health and the environment at the University of California.

But that timeline, she said, would be "quite the feat", given staff turnover and the complications of the process. The EPA is required by law to review and respond to the more than 597,000 comments received on the proposal before moving forwards with a final version.

Dr Woodruff said that the agency is likely to hire contractors to help them go through the comments.

Recent movement

Despite potential headwinds, EPA leadership is apparently proceeding with the rule.

In a 19 April letter to the agency's Science Advisory Board (SAB), Mr Wheeler requested the independent body provide "recommendations on existing mechanisms for data access as necessary to implement" it. Discussion of the science transparency is on the agenda for the SAB's 5 June meeting.

Separately, Dr Woodruff said that a rumour has surfaced that the agency plans to put out a revised version of the rule for public comment. That process, however, remains "unclear".

The EPA would not confirm to Chemical Watch when the rule will be finalised or if a revised proposal is expected. A spokesperson said that the agency "will determine a timeline for a decision after it has more fully assessed the comments".

OMB memo

Meanwhile, the White House's Office of Management and Budget (OMB) has issued a memorandum that revises data processes across the executive branch, including for agencies like the EPA and the Food and Drug Administration (FDA).

The 24 April memo updates the 2002 Information Quality Act (IQA), which sets standards for information used in regulatory functions. And although this action is separate from the science transparency rule, the original proposal of the latter said it was consistent with the 2002 IQA.

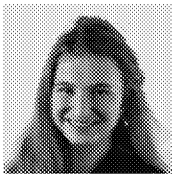
The changes set forth by OMB largely apply to "influential information" that could have a substantial impact on "important public policies or important private sector decisions".

The memo includes several changes that are in line with concepts floated under the science transparency proposal, such as:

- expanding the peer review process;
- increasing public access to data;
- ensuring studies can be reproduced; and
- improving the correction process via increasing agency responsiveness.

The EPA and FDA, among others, have their own information quality guidelines to implement the IQA. The OMB directs agencies to update these internal guidelines within 90 days.

The memo does not constitute a formal rulemaking, so it is not subject to public comment and review.



Lisa Martine Jenkins

Americas reporter

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- Feature: Battle over science rages in US
- US EPA formally issues 'science transparency' proposal
- US EPA's science 'transparency' proposal likely delayed until 2020
- US EPA round-up

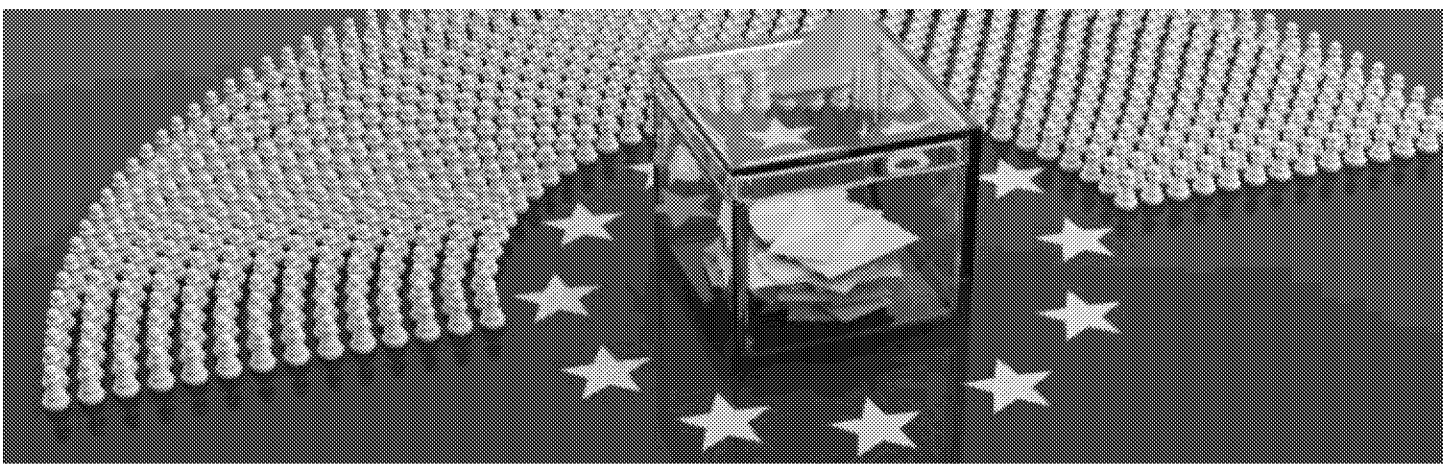
Further Information:

- Science transparency rule
- Wheeler letter to SAB
- OMB memo
- EPA information quality guidelines

NGO Platform: Hazardous chemicals should be a priority for the EU elections

22 May 2019 / Europe, SVHCs

Natacha Cingotti, the senior policy officer leading the chemicals and health programme for the Health and Environment Alliance (HEAL), explains why a non-toxic environment should finally become central to Europe's future.



Chemicals are everywhere, and our exposure to a daily cocktail of chemicals impacts our bodies and health together – yet, according to official data, 75% of the chemicals on the European market are not safe and, so far, European

institutions have failed to take the necessary measures to reduce both environmental pollution and prevent related health conditions.

Although the 7th Environmental Action Programme made it obligatory for the European Commission to develop a strategy for a non-toxic environment by 2018, it has failed to deliver it in this term. As the evidence on chemical pollution and its health impacts continues to increase, commitments to take action to reduce our chemical exposure should be central to the European agenda for the coming term.

With the European elections this week and growing demand from citizens for the reduction of toxic chemical pollution, it is simply absurd to delay the transition to a non-toxic environment, pretending that there is a lack of evidence.

The reality is quite the opposite: we are so swamped with scientific evidence that it is hard to choose which pieces to mention. So here are just a few selected examples:

- Just last week, a European Environment Agency report on the chemical contamination of European seas found that there are some 150,000 chemical substances in commercial use, and a new one is created every 2.5 minutes, without their effects being fully known;
- Eurostats' data, released a few months ago, estimated that 75% of the chemicals produced in the EU are hazardous to health; and
- World Health Organization's data estimates that the burden of disease from just a selected number of chemicals is cutting 1.6 million lives short worldwide.

In addition, when it comes to specific groups of chemicals such as endocrine disruptors, ever-growing evidence points to the need for precaution before putting new chemicals on the market.

Recent conclusions from the Horizon 2020 project EDC-MixRisk found that health effects associated with combined EDC exposures are systematically underestimated. Finally, the latest Global Chemicals Outlook predicts that the goal to minimise the adverse impacts of chemicals and waste for our health and environment will not be achieved by 2020.

Failing to deliver

Despite this evidence, along with the 7th Environmental Action Programme requesting the European Commission to develop a strategy for a non-toxic environment by 2018, and with environment ministers reminding the European Commission of its obligations on several occasions, it has failed to deliver such a strategy to protect citizens' health in this term.

'How much more evidence of chemicals harm to our health do we still need before serious steps are taken to address what, at this point, can only be called an emergency?'

How much more evidence of chemicals harm to our health do we still need before serious steps are taken to address what, at this point, can only be called an emergency?

Undoubtedly, there are powerful commercial interests at play that slow the pace of discussions on identification, classification and regulation of many chemicals of concern.

That's nothing new. What is puzzling and short-sighted is the reluctance to accept the overwhelming evidence and to apply precautionary measures to prevent human exposure to chemicals.

It is especially worrying when, in real-life, we are exposed to several chemicals from different sources at the same time, meaning we need to take into account this so-called chemical cocktail. Considering the high burden of disease from exposure to toxic chemicals, reducing our overall daily chemical cocktail is an obvious opportunity where the EU could make a difference for all Europeans.

 Relying on prevention through a precautionary approach that firmly restricts chemicals being allowed onto the market would not only mean fewer diseases and lower healthcare costs, but also more public funds to research safe alternatives and boost investment to support them.

It is high time for European institutions to realise that more protective chemical policies offer a great chance to increase Europeans' confidence in their decision-makers and that they actually take their concerns seriously and illustrate how Europe can positively contribute to their daily life, their health and that of future generations.

But failing to adequately respond to these well-founded concerns will keep fuelling citizens' distrust. A lot can and should still be done before the autumn.

The European Commission must deliver on its promises when it comes to action on toxics.

Pressing concerns

Most pressing is the revision of the strategy on endocrine disruptors, a fitness check which remains to be launched.

The Commission should also, as soon as possible and in full transparency, release all of the results of the evaluations done on legislations in relation to chemicals under this term, including evaluations of all the chemicals laws, except REACH and the pesticides legislation.

'The EU's overall action on chemicals will continue to lack coherence as long as the overdue non-toxic environment strategy is not developed and released'

The EU's overall action on chemicals will continue to lack coherence as long as the overdue non-toxic environment strategy is not developed and released, a fact that environment ministers have pointed out time and time again.

At their meeting in June, ministers should demand accountability from the European Commission on its commitments for a non-toxic environment.

Commitments to reform the evaluation of chemicals through taking into account the cocktail effect of combined exposures, and looking into families of similar substances rather than one substance at a time are obvious priorities; these should allow for swifter flagging and restricting of chemicals of concern.

Several groups of chemicals of concern have also been singled out on numerous occasions for prioritisation, including endocrine disruptors, flame retardants, highly fluorinated compounds, synthetic pesticides and nanomaterials.

Finally, they should demand commitments to overhaul relevant regulations for chemical exposure in a truly health-protective way, such as that for food contact materials, which are long overdue and should be part of that effort.

Commitments

Candidates and parties running for the European elections should make commitments to improving health and detoxing our economic cycles as a centrepiece of their political programmes.

Those elected as Members of the European Parliament (MEPs) should use their power to question potential European Commissioners in their approval hearings and to ensure that the reduction of chemical pollution is a high priority in the coming five years.

And the next European Commission should place the legal obligation to deliver a meaningful non-toxic strategy at the top of its agenda for health and environment. It remains an important deliverable of the next European Commission and it should guide all other efforts to minimise exposure to harmful chemicals across Europe.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch.

Natacha Cingotti

Health and chemicals policy officer, Health and Environmental Alliance (HEAL)

Related Articles

- EU agency: 7EAP may not meet hazardous chemicals objectives
- NGOs target EU elections in 'detox Europe' campaign
- EDC-MixRisk finds relevant chemical mixtures for risk assessment
- Global Chemicals Outlook II: key findings
- NGOs urge EU ministers to push for stronger action on EDCs

Further Information:

- Green 10 Manifesto
- EEA report
- Eurostat statistics
- World Health Organization figures

US Virgin Islands advances bill restricting sunscreen ingredients

23 May 2019 / Latin America & Caribbean, Personal care

The US territory of the Virgin Islands has become the latest beach community to consider a ban on certain sunscreen ingredients over concerns that they pose a risk to coral reefs and other marine life.

On 20 May, the Virgin Islands' Committee on Government Operations, Consumers and Veterans Affairs unanimously advanced a bill to ban the sale, distribution and import of sunscreen products containing oxybenzone and octinoxate. Originally introduced in March, it is now being considered by the legislature's Committee on Rules and Judiciary.

The bill cites concerns that the two substances – which are contained in many sunscreen and personal care products – have "significant harmful impacts on the Virgin Islands' marine environment and ecosystem". These include coral bleaching and other problems for numerous species, including those protected by the federal Endangered Species Act.

And it says that the chemicals continually enter local waters both because of swimmers and beachgoers, as well as through products washing down the drain, because the territory's wastewater treatment process does not remove them.

The legislation would ban sunscreen products that contain oxybenzone or octinoxate on a staggered timeline, meaning:

- after 31 December 2019, importing them for sale would be illegal;
- after 30 September 2020, selling, offering for sale and distributing them would be illegal; and
- after 1 January 2021, using, possessing or bringing them into the territory would be illegal.

The bill stipulates that violation of the above would result in a fine of $1,000 for the first offence and $2,000 for each subsequent offence.

Virgin Islands action in context

If the bill passes into law, the Virgin Islands will follow Hawaii, Palau, and Key West, Florida in banning products containing these substances.

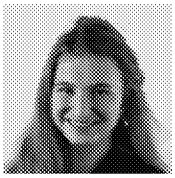
But focus on sunscreen ingredients has also increased at the federal level this year.

In February, the US Food and Drug Administration (FDA) released a proposal to finalise a monograph for over-the-counter sunscreen products, as part of its effort to update its sunscreen product regulations.

The proposal requested more information on 12 ingredients for which the FDA has "insufficient safety data" to confirm that they are 'generally recognised as safe and effective' (Grase). Both oxybenzone and octinoxate were included in this group. If the agency does not receive data sufficient to determine the substances are Grase, they will be required to go through the new drug approval process before they can return to the market.

Meanwhile, the Environmental Working Group has issued its 13th annual guide to sunscreen products and ingredients. It found that 60% of non-mineral sunscreens in the US contain oxybenzone.

The NGO recommends that consumers pick mineral-based sunscreens made with zinc oxide or titanium dioxide.



Lisa Martine Jenkins

Americas reporter

Related Articles

- Feature: Miami Beach is fourth tourist spot to consider sunscreen ban
- Hawaii's governor signs into law ban on two sunscreen ingredients
- Palau to ban ten sun cream ingredients by 2020
- Florida city bans sunscreens containing oxybenzone, octinoxate
- US FDA questions ingredient safety in sunscreen regulations update
- US President signs sunscreen ingredient bill
- Consultation extended on US FDA sunscreen proposal

Further Information:

- Bill 33-0043
- Bill text
- EWG guide to sunscreens

US Senate considers six bipartisan bills addressing PFASs

23 May 2019 / PFCs, United States

The US Senate is considering at least six bills that would address per- or polyfluoroalkyl substance (PFAS) contamination nationwide.

These bills are:

- the PFAS Action Act of 2019 (S 638) – requiring the EPA to list PFASs as hazardous substances under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Cercla), or Superfund;
- the PFAS Detection Act of 2019 (S 950) – directing the US Geological Survey (USGS) to perform a nationwide survey of PFASs;
- the Safe Drinking Water Assistance Act of 2019 (S 1251) – improving and coordinating interagency federal action and assisting states in responding to health challenges posed by "emerging contaminants";

- the PFAS Accountability Act of 2019 (S 1372) – encouraging federal agencies to cooperate with states to remove and remediate PFAS contamination in water sources and on land;
- the Protect Drinking Water from PFAS Act of 2019 (S 1473) – requiring the EPA to set maximum contaminant levels for certain chemicals; and
- the PFAS Release Disclosure Act (S 1507) – including certain PFASs in the Toxics Release Inventory (TRI).

All have bipartisan sponsorship, a fact that was highlighted at a 22 March hearing held by the Committee on Environment and Public Works.

Senator Sheldon Whitehouse (D-Rhode Island) urged the EPA to avoid "injecting partisanship" into the regulatory process, noting that "bipartisanship is a terrible thing to waste".

The House of Representatives is also considering 13 bills on the substances. It held a hearing on 15 May to discuss them.

Related Articles

- US Congress round-up

Further Information:

- Hearing video

Echa round-up

23 May 2019 / Europe, REACH

Consultations on applications for authorisation

Echa is looking for comments on 11 applications for authorisation covering 18 uses of:

- chromium trioxide used in surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices;
- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-nonylphenol, branched and linear, ethoxylated used in the production of various medical devices and medicinal products; and
- pitch, coal tar, high-temperature, used in the manufacturing of thermally and thermo-mechanically highly loaded carbon/carbon parts for aerospace launchers.

The deadline for comments is 17 July.

CLH public consultations

The agency has invited comments on CLH proposals for:

- 2-(2-methoxyethoxy)ethanol. Proposed by the Netherlands it is primarily used as an intermediate or industrial processing aid and an additive in aviation fuels;
- pyridine-2-thiol 1-oxide, sodium salt. Proposed by Sweden it is an active substance mainly used in biocidal products as a preservative and disinfectant; and

- methyl methacrylate methyl 2-methylprop-2-enoate. Proposed by the Netherlands, it has several uses including adhesive and sealants, and as a monomer for polymerisation or intermediate in synthesis of other chemicals.

The deadline for comments is 5 July.

Registration improvement tips

In an article in this month's Echa newsletter the agency gives five top tips for improving REACH registration dossiers. These are:

- identify the substance correctly;
- include physico-chemical, toxicological and environmental information;
- when applying a read-across approach, justify the hypothesis well;
- update dossiers regularly; and
- classify substances correctly.

The agency points out that it is the registrant's responsibility to classify and label its substance properly.

"There is plenty of information available to improve compliance. Check this information and build a process in your company to make sure your registration dossiers are up to date and compliant," the article adds

Webpages: database of articles containing SVHCs

The agency has created webpages on the database it is developing for information on articles containing substances of very high concern from the candidate list, under the waste framework Directive.

The webpages provide background information and details about the project's next steps.

Companies producing, importing or supplying such articles will need to submit information to Echa from January 2021.

Echa closed dates

The agency will be closed on 30 and 31 May.

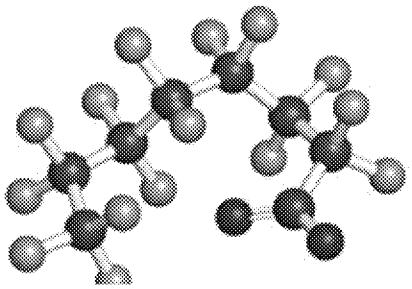
This article contains some information published in the Echa round-up of 17 May.

Further Information:

- Authorisation consultations
- CLH public consultations
- Registration tips
- Articles containing SVHCs

NGOs criticise EU for requiring exemption from global PFOA ban

23 May 2019 / Alternatives assessment & substitution, Europe, PFCs, POPs



A group of international NGOs has criticised the EU for requiring an exemption for medical textiles from a global ban on the use of perfluorooctanoic acid (PFOA) agreed at the UN Conference of the Parties (COPs) earlier this month.

In a 10 May statement, NGOs, including the Health and Environment Alliance (HEAL), Health Care Without Harm (HCWH) and Arnika, expressed "deep regret and disapproval" for the request, which could "undermine an otherwise effective worldwide ban".

Delegates from more than 180 countries agreed the prohibition of the use of the chemical, adding it to Annex III of the Stockholm Convention at the conference in Geneva.

However, several exemptions for the substance, including one for medical textiles, were requested by the EU delegation – along with China and Iran – and approved.

PFOA is widely used for its resistance to water and oil. PFOA-related compounds are used as surfactants and surface treatment agents in textiles, papers and paints and firefighting foams. The substance has been identified as persistent, bioaccumulative and reprotoxic by the EU.

The NGOs said the exemption goes "against the recommendations from the POPs Review Committee for the Stockholm Convention", which identified several potential alternatives to PFASs for use in medical textiles, but no specific applications "absolutely" requiring a PFOA use.

During the COPs talks, the NGOs said even representatives of the fluorochemicals industry "repeatedly opposed this exemption request", because of the "wide availability of existing alternatives to the substance".

The NGOs also blamed the EU for requesting the exemption during the meeting, after having previously nominated PFOA for listing under the Stockholm Convention, and participating in the evaluation process – during which exemptions should normally be listed.

This behaviour, they said, shows "a very disturbing disrespect of the UN's careful review process and illustrates the EU's flagrant disregard of the accepted protocol for listing exemptions under the Stockholm Convention".

In requesting the exemption, the chemicals policy and projects officer at HCWH Europe, Dorota Napierska, added, "the EU has effectively lowered the bar in global chemicals management and brought other countries in line with its own weak regulation".

This, she added, will have a "significant direct impact" on the amount of PFOA released into the environment as the substance is used in significant amounts in the treatment of medical textiles.

NGOs called on the EU to "change its behaviour" and "truly embrace its powerful mandate" demonstrating a strong leadership in protecting the environment.

Caterina Tani

Europe reporter

Related Articles

- UN meeting adopts amendments to international conventions
- Firefighters call for fluorine-free foam at international POPs meeting
- Geneva meeting agrees global ban on PFOA, with exemptions
- Perfluorinated chemicals: a persistent problem

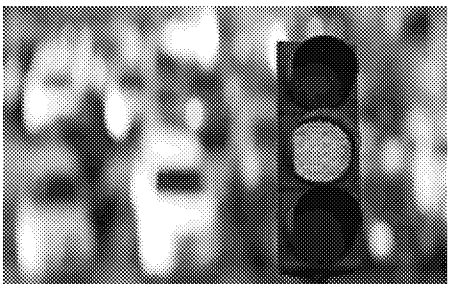
Further Information:

- NGOs paper

Further delays expected for US HazCom standard update

Spring regulatory agendas largely reflect expected timelines

23 May 2019 / Hazcom Standard, TSCA, United States



The timeline for the US to update its Hazard Communication Standard (HCS) has again been pushed back, according to the semi-annual release of the Department of Labor's regulatory agenda.

The HCS was significantly amended in 2012 to bring the US's hazard communication programme in line with the third version (Rev 3) of the UN's Globally Harmonized System (GHS) of classification and labelling of chemicals. But the scheme - which is intended to lay out a common system for classifying chemicals and communicating hazard information through labels and safety data sheets - has not been updated since, even while the GHS 'purple book' was updated in 2017 to its seventh version.

The Occupational Safety and Health Administration (Osha) indicated in its autumn 2014 regulatory agenda plans to update the HCS. Two years later, it set an October 2017 target for a notice of proposed rulemaking (NPRM), but that goal was not met. Subsequent agendas saw the timeline shift to February of this year (according to the spring 2018 agenda), and then to March (under last autumn's update).

However, the spring 2019 regulatory agenda, released this week, shows further delays to the update. The NPRM is now slated for December 2019.

Osha did not respond to a request for comment by press time as to what had caused the delays.

Other agency activity

Activities related to chemicals in the regulatory agendas of other US agencies generally reflect expected timelines for ongoing activities and statutorily imposed deadlines.

The EPA's agenda, for example, includes:

- a proposed TSCA risk management rule for certain persistent, bioaccumulative and toxic (PBT) chemicals to be issued by the 21 June deadline imposed by the Lautenberg Act;
- finalising the Strengthening Transparency in Regulatory Science rule by December, in line with reports heard in recent weeks;
- finalising changes to the TSCA Chemical Data Reporting (CDR) rule by the year's end;
- issuing a final procedural rule for the substantiation and review of TSCA confidential business information (CBI) claims by February 2020 – one year after the release of an updated inventory;
- releasing an updated proposal for significant new use rules (Snurs) on certain long-chain perfluoroalkyl carboxylate (LCPFAC) substances by September.

The agency also added to its agenda plans to add certain per- and polyfluoroalkyl substances (PFASs) to the Toxic Release Inventory (TRI) programme. An advanced notice of proposed rulemaking (ANPRM) is expected this autumn.

Meanwhile, new to the Consumer Product Safety Commission's (CPSC) regulatory agenda is a proposal to reduce the burden of third-party testing requirements for children's products with respect to certain manufactured fibres.

A timeline on the agency's consideration of a petition to ban organohalogen flame retardants from certain products, however, has no further details beyond the May release of a National Academies feasibility study.

The 'unified agenda of regulatory and deregulatory actions' is released each spring and autumn by the Office of Information and Regulatory Affairs (Oira).

Kelly Franklin

North America editor

Related Articles

- Guest Column: A glimpse at US Osha's updated hazard communication standard
- Osha to align US rules with latest GHS
- Academics, NGOs protest TSCA PBT risk review approach
- US EPA looks to move on controversial science transparency rule
- US EPA proposes amendments to CDR rule
- US EPA issues proposal for CBI substantiation
- EPA releases updated TSCA inventory
- US EPA proposes Snur for perfluoroalkyl carboxylates
- Putting toys to the test
- US CPSC investigates possible action against organohalogen flame retardants
- National Academies backs class-based OFR assessments in US

Further Information:

- HazCom agenda entry
- EPA agenda
- CPSC agenda

Sanger Institute announces closure of animal research facility

23 May 2019 / Risk assessment, UK

The Sanger Institute has announced it is to close its animal research facility near Cambridge due to a rise in the use of alternative technologies.

The British genomics and genetics research institute's decision was driven by a scientific strategy that came after a review and consultation. Sir Mike Stratton, director of the Wellcome Sanger Institute, said "this has been a difficult decision, but we believe it is the best way to continue to deliver the science and make the discoveries that impact on human health and the natural world".

The closure, which is scheduled to happen over the next few years, is a result of the increasing use of alternative technologies, which has led to fewer mice being needed. "Scientific research involving mice will remain an important part of Sanger Institute science, and will continue at reduced levels in the future," added Professor Stratton.

The mice will be transferred to another facility, according to the Institute. Discussions about this change and which institutions will be taking on this task are ongoing.

Animal rights organisation Peta UK welcomed the news that the facility is scaling back its use of animals in experiments. Their senior projects and science policy advisor, Dr Julia Baines, said "the Sanger Institute would be better off focusing on human-relevant methods, such as its work using realistic three-dimensional tumour models grown from tissue samples taken from cancer patients".

Dr Jarrod Bailey, senior research scientist for Cruelty Free International, felt that this was a courageous decision and one that will hopefully set a precedent for others who are looking at moving away from animals into the use of alternative technologies.

"There's an increasing realisation that animals don't serve as very good models for humans," according to Bailey. "Whether that's in basic or disease research, or testing for efficacy and toxicity of new drugs and chemicals, there's now quite overwhelming evidence that it's not a good approach."

Note: Your access to this subscriber-only article is through a corporate subscription

Maria Delaney

Reporter

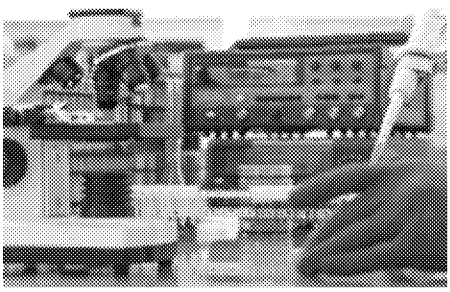
Further Information:

- Announcement

Ecetoc publishes conceptual framework for polymer risk assessment

Includes intentionally-added substances and impurities

23 May 2019 / Europe, Risk assessment



The European Centre for Ecotoxicology and Toxicology of Chemicals (Ecetoc) has developed a 'conceptual framework' for polymer risk assessment called CF4Polymers. A task force has reviewed polymer grouping and risk assessment procedures to provide guidance for assessing potential ecological and human health hazards and risks.

The report takes into consideration the fact that polymers are diverse and complex, containing intentionally-added substances, such as stabilisers or UV-stabilisers, as well as impurities and contaminants. Polymers can also change form during different lifecycle stages.

Polymers tend to be listed and named based on the chemical composition of the principal monomers used to make them. This means that a wide range of polymers that vary in terms of unreacted monomers, physical form and chemical reactivity can have the same Chemical Abstract Service (CAS) name and number, explains the report.

The framework includes using expert knowledge to determine all structural descriptors as well as physicochemical and fate properties relevant for risk assessment. Polymer identification should also include intentionally and non-intentionally added substances.

The report represents "the first time that the polymer risk assessment process not only addresses the polymer itself, but also any potential impurities or added substances," said Olivier de Matos, Ecetoc secretary general. "It is anticipated that the guidance will evolve in light of future developments in the state of knowledge," he added.

The framework outlines eight steps, from polymer identification to exposure scenarios, hazard assessment and risk characterisation.

It contains advice on how to determine polymer similarity for grouping purposes, including setting a hypothesis, such as whether polymers have the same molecular initiating event for a given endpoint.

The report points out that some analytical tools have "technical limitations" restricting their suitability for assessing polymers. The task force is working on a review of the applicability of tools, methods and models to assess the different properties of polymers.

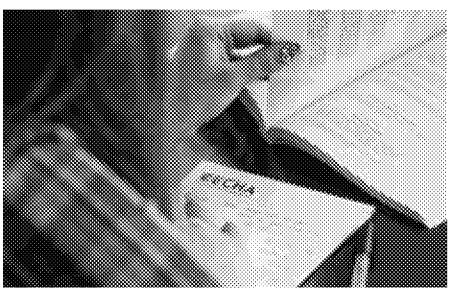
Further Information:

- Technical report

Cefic, regulators promise action on REACH dossier non-compliance

NGO criticisms question legality not quality; industry says arguments are 'simplistic'

23 May 2019 / Europe, REACH



In the wake of stinging criticism from NGOs, Cefic says it is committed to making REACH dossiers compliant and is already working on preparing an action plan with Echa and the European Commission to address data gaps.

The NGOs' claims, which have been widely reported in the press and were picked up by the European Parliament, came just as Echa was announcing plans to raise the number of compliance checks from 5% to 20% for each tonnage band.

The day before a key Echa stakeholder conference in Helsinki this week, Germany's Friends of the Earth (Bund) issued a press release naming hundreds of chemical, cosmetics, pharmaceutical and food companies it said are "breaking the law", because their substance registration dossiers are non-compliant with data requirements.

Bund analysed data from a freedom of information request to the German government, which investigated chemical safety files from 2014 and concluded that 940 substances failed REACH data safety standards.

Cefic promises to act – but needs Echa's help

Responding to the NGO's claims at Echa's conference yesterday, Cefic product stewardship director Sylvie Lemoine said the chemical industry is committed to making REACH work. "We have invested heavily. We want people and the environment to be safe."

The German government's work "has been useful and we have been encouraging our members to contact them for feedback. But let's be clear, the work of [these agencies] is not a compliance check," she said.

Stating that, based on this work, there are substances on the market illegally "is a pretty simplistic statement", Ms Lemoine said. Industry, she added, wants to hear from the German authorities to understand the shortcomings. "We take this very seriously and we're determined to act."

Ms Lemoine told delegates that the CEOs and business presidents of its board member companies met last week and discussed the allocation of resources that its members would need to make for further testing. Companies will allocate resources to the task and do further testing where needed but they "need to be sure what information is missing and what will be enough to pass a compliance check – that's where we need the support of Echa". Cefic will also report on progress against the plan, on which it hopes to be able to say more by the summer.

The fact remains, however, that there is no model for a perfect dossier, she added. Industry, "only hears when there has been a problem" with the compliance check, but Echa "doesn't tell us what we should be doing" to avoid problems. "That's where we need to work together. We need positive and timely feedback."

Industry is keen to take action, she said, but "naming and shaming is not helpful". The companies know about the issue and have been discussing it for six months, she added. "Maybe we could have communicated more about what is happening."

More compliance checks

Echa and the Commission are preparing a joint action plan, to be finalised by July, containing "concrete actions" on compliance to be completed by the end of 2027. The Commission is also preparing an implementing Regulation that will change the current text of REACH Article 41(5) and raise the target for the number of compliance checks Echa must conduct from 5% to 20% for each tonnage band.

Echa has said for some time it agrees that registration compliance must be improved. Last year, executive director Bjorn Hansen told a committee of MEPs the agency was "concerned" about Germany's findings and promised further action. But the system, he said, is set up for the companies to stay on the market. "They are not illegally on the market," he said. "The system is set up so all these dossiers are complete, but a high fraction are not compliant."

Speaking to Chemical Watch, Echa's director of hazard assessment Christel Musset said some of Bund's claims were incorrect. "If the data is not there, the dossier doesn't pass the completeness check. There is confusion very often between completeness and compliance."

Also, some of the substances mentioned are already regulated, she said – for example, they may be classified or identified as an SVHC. "But the reality is that many dossiers are still incompliant. We are committed to do[ing] something about it."

The "big discussion" Echa and industry are having, Ms Musset said, is that "the dossiers are complete but we don't agree with the way they have been put together and the justification for not providing information".

The agency also refuted claims that registrant information is inaccessible. All the company names are on Echa's website, Ms Musset said, but added that "maybe it's not easy" for those unfamiliar with the website to find them. "That is where we need to work. We really need to improve the transparency of our [...] website ... and we need to help people find this information."

Tip of the iceberg?

Tatiana Santos, chemicals policy manager at the European Environmental Bureau, an umbrella group to which Bund belongs, told the conference naming and shaming of companies is a "right for the public" and that the "very high level" of non-compliance is not acceptable. "We hear it is about quality. No, it is about legality".

The German assessment, she said, was much more clear than Echa's because it checked what data was available for each substance and endpoint and then whether that data was missing from the dossier.

Echa has launched "soft" measures, she added, but they are not working and stricter measures and sanctions are necessary.

Because the public is left in the dark on enforcement, there is a lack of trust, she added. And because information is only available for a small number of substance registrations, it could be "just the tip of the iceberg".

Bund and the EEB want Echa to "clearly identify" all non-compliant substance dossiers and responsible firms in its main database and "retrospectively check non-compliant dossiers identified by [the German government] for completeness, as well as improve, increase and speed up its compliance checks". National authorities "should increase transparency and impose tougher sanctions, including fines, name and shame or criminal proceedings without delay".

Companies under spotlight

Bund released an analysis of data it obtained from a freedom of information request to the German government in 2015 following an assessment of the registration dossiers for high-tonnage substances by Germany's Federal Institute for Risk Assessment (BfR), which found many had inadequate safety data.

The final study, published by the BfR in November, said the average rate of "compliance" for high-tonnage substances was 31% and that alternative data, for example from read-across, or justifications for data waiving were often insufficient. Some 32% of the dossiers for substances at tonnage levels above 1,000 tonnes a year were "non-compliant" with REACH requirements on average over the assessed endpoints.

Six months before its final report came out, the BfR, says Bund, gave the names of the 940 substances it had assessed as "non-compliant". The NGO was unable to verify whether most of the substances remain non-compliant today, but of the 240 dossiers it has had access to, 41 had not been updated between 2014 and 13 April 2019 – the date it concluded its analysis. More than 600 companies are identified in these dossiers as registrants.

Bund's release said five of the global top 10 chemical companies by sales are implicated: BASF, Dow Chemical, Ineos, ExxonMobil and SABIC.

Chemical Watch contacted them and only two had responded by the deadline. Ineos said industry is working with Echa to identify areas where improvements may be required.

BASF, which has the largest number of REACH registrations, said it has prepared the dossiers "with diligence and to the best of its knowledge". It has "fulfilled" legal obligations to update dossiers, it added, and has procedures in place to check their status.

Cefic and Echa, BASF pointed out, are preparing a cooperation agreement to further improve registration dossier quality on a voluntary basis. "BASF supports this initiative and is actively working on its design."

BASF legal entities have registered nine out of the 41 substances in the Bund release. BASF says it does not serve as the lead registrant for any of them.

Luke Buxton

Europe editor

Related Articles

- Echa to raise number of compliance checks to fifth of REACH dossiers
- REACH registration project finds low compliance rates
- Cefic and Echa sign agreement to improve REACH implementation

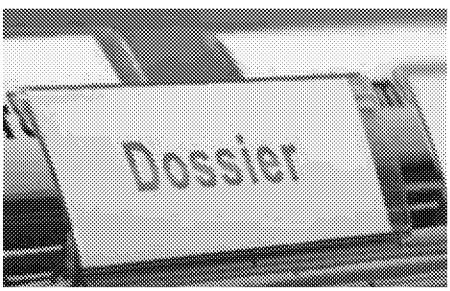
Further Information:

- Bund press release
- Echa conference

Echa to raise number of compliance checks to fifth of REACH dossiers

Agency also plans 'concrete' actions on authorisation after court rulings

23 May 2019 / Europe, REACH, Substance registration



Echa is to quadruple the number of compliance checks it carries out to a fifth of all REACH registration dossiers in a fresh attempt at tackling non-compliant information on chemicals.

The increase in checks from 5% to 20% of dossiers registered by the 2018 deadline comes as part of a joint action plan Echa is preparing with the European Commission to "fix" the poor compliance of REACH dossiers, the agency said.

In the plan, to be published in June, Echa said it will endeavour to screen all registered substances above one tonne by 2027 and check the compliance of "all substances that need it". These include, for example, substances with hazardous properties, or where more data needs to be generated to conclude a potential risk.

Compliance has been a key concern in REACH implementation. In February, the agency revealed that information was missing from almost 75% of all dossiers. And a major exercise by German authorities last year found a third of dossiers at tonnage levels of 1,000 tonnes a year (tpa) and above to be non-compliant.

Echa says the main reasons for non-compliance are:

- unjustified waiving of data requirements;
- data gaps for higher tier substances; and
- insufficient documentation.

With the changes, the agency estimates that 30% overall of the registered substances will be "concerned" by a compliance check, corresponding to about 20% of all dossiers received by the 2018 registration deadline.

Substances registered above 100 tpa will face compliance checks in about 35-40% of cases, Echa said.

The total number of substance registrations that include the full set of information required is currently 70,442, covering 15,800 substances. In the past 10 years, Echa has checked more than 2,700 dossiers for compliance.

Efficiency increase

Echa's efforts to boost compliance are in response to the Commission's second REACH Review, which called for actions to improve dossier updates and evaluation procedures.

As part of the forthcoming action plan on compliance, Echa will also increase the efficiency of dossier checks by simplifying its decisions and "further improving" the efficiency of the evaluation process, it said.

Other objectives are to give more clarity to legal provisions, accelerate the decision-making process and improve enforcement, Ofelia Bercaru, head of unit, hazard, told an Echa stakeholder conference in Helsinki on 22 May.

Since the beginning of the year, the agency has been shifting resources internally to increase efforts and streamline the evaluation work, executive director Bjorn Hansen said in a newsletter.

Echa has also asked national enforcement authorities (NEAs) from EU member states and the EEA to tackle non-compliance around REACH evaluation decisions as a priority. And from January, it started to extend decisions concerning these checks to all registrants, not just the lead registrant, of a substance.

Changes in authorisation

Separately, the agency is studying the implications of two court rulings on authorisation, both internally and with the Commission, to identify how the authorisation system would need to be adapted "in the short and longer term".

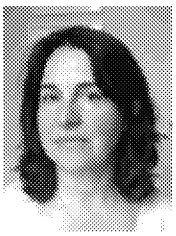
It intends to change how the opinions are documented "so as to increase their clarity and consistency in decision making", a spokesperson said. Echa will discuss this in the forthcoming meetings of the risk assessment and socio-economic analysis committees (Rac and Seac) in June.

The Echa management board will also debate Echa's planned actions at its June meeting.

Mr Hansen said the first "concrete" actions on how to improve the authorisation process would be announced during the summer.

The agency is particularly looking into concerns that upstream applications made by manufacturers or importers do not adequately cover downstream uses and conditions.

"I am committed to working with the Commission, member states and the applicants to improve this," Mr Hansen said.



Clelia Oziel

Europe correspondent

Related Articles

- EU plans data check for all chemicals above one tonne by 2027
- Information missing from three-quarters of REACH dossiers
- REACH registration project finds low compliance rates
- EU publishes delayed second REACH Review
- EU enforcers to prioritise evaluation decisions
- Major revamp of REACH dossier compliance processes announced
- EU to appeal court judgment on lead chromate authorisation
- ClientEarth loses landmark case on recycled PVC authorisation

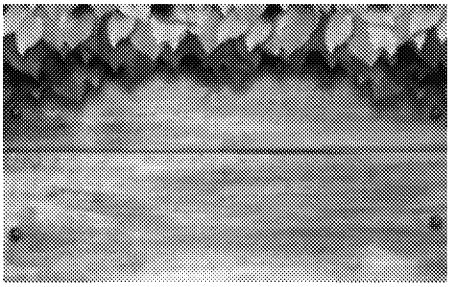
Further Information:

- Press release
- Newsletter

Study: copper in wood preservatives may induce liver toxicity

Concerns that people could ingest nanoparticles

23 May 2019 / Academic studies, Biocides, Built environment, Europe, Nanomaterials



Copper oxide and copper carbonate nanoparticles used as antimicrobial agents and wood preservatives may induce liver toxicity, in addition to causing changes in multiple organs, if ingested, according to a rodent study.

Led by Wim De Jong from the National Institute for Public Health and Environment (RIVM) in the Netherlands, a European group from academia and industry estimated the oral toxicity of the copper compounds, assuming that people could ingest the chemicals through hand-to-mouth transfer.

Copper is the most widely used fungicide for treating wood in contact with soil as it is the only biocide that shows significant effects against soil-borne fungi. It is a preferred wood preservative due to its minimal effect on mammals, including humans, although it shows a relatively high toxicity against aquatic communities.

Solid copper carbonate needs to be micronized by milling to generate particle sizes able to penetrate into the wood during pressure treatment. But the study authors could find "no publications available on oral toxicity of this micronized copper carbonate", they report in the journal *Nanotoxicology*.

Both nanoparticles induced changes in haematology parameters and clinical chemistry markers indicative of liver damage. Organ damage in the GI-tract, kidney, and the lymphoid organs (spleen, thymus) were more severe for copper carbonate compared with copper oxide nanoparticles.

The researchers looked at the dissolution characteristics of the nanoparticles in both stomach and intestine conditions. The primary particles simultaneously shrank and agglomerated into large structures in the intestine which led the researchers to conclude that "both copper ions and the particulate nanoforms should be considered as potential causal agents for the observed toxicity".

The team calculated bench mark doses for the copper chemicals, giving values "surprisingly similar" to the no-observed-adverse-effect-level (Noael) for copper sulfate, where the copper ion is "likely the main toxicant".

The researchers suggest that copper ions may play an important role in the mechanism of copper nanomaterial toxicity. Their data also identified that the immune system may be "severely affected" by these copper ions, matching their findings on silver nanoparticles.

"In view of the potentially high migration of nanomaterials to the spleen, the immune system may be a target for nanomaterial toxicity and needs consideration for a more specific toxicity evaluation", they write.

They suggest that their data may be useful for deriving an acceptable daily intake for wood preservatives.

Maria Delaney

Reporter

Further Information:

- Journal article (open access)

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